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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/374,142	08/11/1999	HENRY C. LIN	P07-42146	3370

7590 04/22/2003

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EXAMINER
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NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/374,142

Applicant(s)

Lin et al

Examiner

Mark Navarro

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12-30 and 56-79 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-30 and 56-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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**DETAILED ACTION**

Applicant's amendment filed February 10, 2003 (Paper Number 19) has been received and entered.

New claims 67-79 have been added, consequently claims 12-30 and 56-79 are pending in the instant application.

***Claim Rejections - 35 USC § 112***

1. The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the use of the phrase "derivative." is withdrawn in view of Applicant's amendment.

***Claim Rejections - 35 USC § 102***

2. The rejection of claims 12 and 56 under 35 U.S.C. 102(b) as being anticipated by Rutgeerts et al is withdrawn in view of Applicant's amendment.

***Claim Rejections - 35 USC § 103***

3. The rejection of claims 12, 21-23 and 56 under 35 U.S.C. 103(a) as being unpatentable over Rutgeerts et al in view of Wellmann et al and Friedman is withdrawn in view of Applicant's amendment.

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The following new grounds of rejection are applied to the amended claims:

***Claim Rejections - 35 USC § 112***

4. Claims 12-30, and 56-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treatment of bacterial overgrowth comprising detecting small intestinal bacterial overgrowth and at least partially eradicating the bacterial overgrowth, does not reasonably provide enablement for treatment of the autoimmune disease systemic lupus erythematosus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to a method of treating irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, ADHD, or an autoimmune disease selected from the group consisting of multiple sclerosis and systemic lupus erythematosus, comprising: detecting the presence of small intestinally bacterial overgrowth in a human subject having at least one symptom associated with a suspected diagnosis of irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, ADHD, or an autoimmune disease selected from the group consisting of multiple sclerosis and systemic lupus erythematosus; and at least partially eradicating the bacterial overgrowth, whereby the at least one symptom is improved.

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Way (Current Surgical Diagnosis & Treatment, 9th Edition, 1991, page 1083) sets forth that systemic lupus erythematosus is an autoimmune disease in which the presence of **anti-DNA antibodies** are diagnostic. (See page 1083). In other words, a patients own immune system is attacking its own cells. Applicant's specification sets forth in Example 5, 15 patients which had been diagnosed with SLE, and of these 15 patients, 13 had bacterial overgrowth, as indicated by LBHT. Applicant's specification further sets forth of administering neomycin to these patients, and reports decreased joint pains, gas and fatigue in 4 patients. However, the antibiotic which would certainly eradicate the bacterial overgrowth and lead to decreased gas, does not "treat" systemic lupus erythematosus. The presence of anti-DNA antibodies which would continue to react with the patients own DNA, would remain unchanged and unaffected. The disease itself, remains unaffected. Applicant's have effectively treated the bacterial overgrowth, however, this is not commensurate in scope with the treatment of SLE, as set forth in the instantly filed claims.

In view of the lack of guidance, lack of working examples, and unpredictability in the art one of skill in the art would be forced into undue experimentation to practice the broadly claimed invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

April 21, 2003